1030 Eskdale Road
Winnersh Triangle
Wokingham
RG41 5TS
www.BD.com

14 March 2022

PRODUCT NOTIFICATION – MDS-22-4341

Product Name: BD Plastipak™ Syringe, 20 mL

REF: 300613 **Lot Number:** 2106055

Type of Action: Advisory

Dear Valued Customer,

BD is issuing this advisory product notification for lot number 2106055 of **BD Plastipak™ Syringe** (catalogue number/REF: 300613, 20 mL syringe) due to incorrect primary packaging labelling. According to our distribution records, your organisation may have received the impacted product.

Description of the Problem:

BD has become aware through customer feedback that a percentage of **BD Plastipak™ Syringe** (catalogue number/REF: 300613, lot number 2106055, 20 mL syringe) have the potential to be mislabelled as a BD Plastipak™ 50 mL Catheter Tip Syringe (catalogue number/REF: 300867) on the primary packaging label. This issue is estimated to affect less than 10% of devices manufactured for this lot. The expiry date and lot information on the affected packaging is listed correctly. All other levels of packaging correctly identify the product as **BD Plastipak™ Syringe** (catalogue number/REF: 300613, lot number 2106055, 20 mL syringe). The sterility of the device is not compromised. Figure 1 below depicts an example of the incorrect primary packaging.

Figure 1. Example of the incorrect primary packaging.

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This advisory is limited to the lot number 2106055 of **BD Plastipak™ Syringe** (catalogue number/REF: 300613, 20 mL). No other product codes or lot numbers are affected.

There is no requirement for customers to return any BD Plastipak™ Syringe to BD. These products can continue to be used in accordance with the guidance in this notification.

Clinical Risk:

A mislabelled device may cause a delay in treatment as the clinician may not be able to use the contained syringe for the intended medical intervention. However, this should be mitigated by the accepted good clinical practice, of inspecting products to ensure that they are suitable for their intended use. Clinicians are likely to become aware of the discrepancy between the two syringe sizes by handling the packaging and further inspection of the label and the product contained within the packaging assists in reducing the risk for delay in treatment. The need to replace the mislabelled syringe may lead to clinician/user dissatisfaction.

To date there have been no reported adverse events worldwide related to this issue.

Actions BD has taken:

BD has identified the root cause and is taking corrective actions to prevent recurrence of this issue.

Actions for Customers to take:

For existing **BD Plastipak™ Syringe** users, BD requires that the actions below are taken:

1. Circulate this product notification to all those within your organisation that may use the **BD Plastipak™ Syringe** (catalogue number/REF: 300613, lot number 2106055, 20 mL).

2. If you have further distributed the product, please identify those users and notify them at once of this advisory.

3. If you experience this mislabeling with the **BD Plastipak™ Syringe**, report as a complaint to BD per your normal process.

4. Complete the Customer Response Form on page 4 and return it to BDUKFieldAction@bd.com **as soon as possible but no later than 11 April 2022.** If you no longer use the product, it is still important that you return the Customer Response Form for our reconciliation purposes.

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Contact Reference Person

If you have any questions about this, please contact your local BD representative.

BD is committed to advancing the world of health. Our primary objectives are patient safety and user safety and providing you with quality products. We apologise for the inconvenience this situation may cause you and thank you in advance for helping BD to resolve this matter as quickly and effectively as possible.

Sincerely,

Lorna Darrock
Sr. Manager, Post Market Quality
EMEA Quality

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Customer Response Form – MDS-22-4341

BD Plastipak™ Syringe, 20 mL

REF: 300613 **Lot Number:** 2106055

Please read in conjunction with product notification MDS-22-4341 and return the completed and signed form as soon as possible or **no later than 11 April 2022** to BDUKFieldAction@bd.com.

By signing below, you confirm this notice has been read, understood and that all recommended actions have been implemented as required.

Name of Trust / Organisation			
Your Facility Address			
Postcode			
Telephone number		**E-mail address**	
Name of your supplier for this product *(if not direct from BD)*			

	Facility / Hospital Name	**Postcode**
Please list all Facilities / Hospitals covered by your response* *(e.g. other sites within your Trust / organisation.)*		

**Please note that you may still receive reminder notifications if you cover multiple impacted sites but do not declare these above.*

Your Name		**Job Title**	
Signature		**Date**	Submit Form

This form must be returned to BDUKFieldAction@bd.com before this action can be considered closed for your account. If you were forwarded this Field Safety Notice via a distributor/3rd party, please return your completed form to that organisation for reconciliation purposes.